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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/555,704	06/02/2000	Toyokazu Ishikawa	9150-0008.10	9123

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PERKINS COIE LLP  
P.O. BOX 2168  
MENLO PARK, CA 94026

EXAMINER

BROWN, STACY S

ART UNIT	PAPER NUMBER
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1648

DATE MAILED: 06/13/2002

15

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/555,704	ISHIKAWA ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Stacy S Brown	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 27 February 2002.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-3,5,7,9,10,13 and 15-18 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3,5,7,9,10,13 and 15-18 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 02 June 2000 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                   | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                          | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>13</u> . | 6) <input type="checkbox"/> Other: _____                                    |

### **DETAILED ACTION**

1. Applicant's amendment filed February 27, 2002 is acknowledged and entered. Claims 4, 6, 11, 12 and 14 are cancelled. New claims 17 and 18 are added. Claims 1-3, 5, 7, 9-10, 13 and 15-18 are pending and examined.
2. The objection to claims 5 and 13 is withdrawn in view of Applicant's amendment. The objection to the specification is withdrawn in view of Applicant's amendment to the abstract. The rejection of claims 1-7, 9 and 11-16 under 35 U.S.C. 102(a) as being anticipated by Huiying et al. (1998) or Takegami et al (1998) is withdrawn in view of Applicant's amendments. The rejection of claims 1-7, 9 and 11-16 under 35 U.S.C. 102(b) as being anticipated by Huiying (1995) is withdrawn in view of Applicant's amendments. The rejection of claims 1-7 and 9-16 under 35 U.S.C. 103(a) is withdrawn in view of Applicant's amendments.
3. The Supplemental Information Disclosure Statement submitted March 11, 2002 is considered.

### ***Claim Rejections - 35 USC § 102***

4. Claims 1-3, 9, 15, 17 and 18 are rejected under 35 U.S.C. 102(a) as being anticipated by Ding et al (*Zhonghua Yi Za Zhi* (Nat'l. Med. J. China) 1998, 78:261-262). The claims are drawn to an inactivated virus particle and method of preparing inactivated virus particles from a culture of cells (Vero) infected with JEV, wherein the particles are inactivated and purified. The particles elicit neutralizing antibody titers 2 to 10 times higher than particles obtained from mouse brain cultures. The inactivated particles are used in vaccines. Electron microscopy of the particles reveals a rough or fuzzy surface (or envelope layer).

Art Unit: 1648

Ding teaches the production of purified Japanese encephalitis vaccine from Vero cells with roller bottles. The virus was inactivated, concentrated, treated with protamine sulphate and purified. The properties of eliciting antibody titers and appearance with electron microscopy are inherent properties of the particles of Ding. Since the product of Ding and the product of the instant invention are made by the same method steps, the two products are identical and therefore any property associated with the particle and method of producing are inherent.

***Claim Rejections - 35 USC § 103***

5. Claims 1-3, 5, 7, 9-10, 13 and 15-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ding (as applied to claims 1-3, 9, 15, 17 and 18 in the 102(a) rejection) or Huiying et al (1998), and further in view of Liau et al (6,207,439). The claims are drawn to an inactivated virus particle and method of preparing inactivated virus particles from a culture of cells (Vero) infected with JEV (Beijing or RhCMAR67/93), wherein the particles are inactivated and purified. The inactivation step is conducted between 4 and 10 degrees Celsius. The particles elicit neutralizing antibody titers 2 to 10 times higher than particles obtained from mouse brain cultures. The inactivated particles are used in vaccines or diagnostic kits. Electron microscopy of the particles reveals a rough or fuzzy surface (or envelope layer).

The teachings of Ding are summarized above and the teachings of Huiying have been made of record. Huiying is silent on the step of inactivation, though the title of the reference clearly indicates that the virus was inactivated. Ding sets forth steps of inactivation followed by purification. One would have been motivated to modify Huiying with the method steps of Ding because Ding teaches inactivation, and Huiying teaches an inactivated virus. One would have

Art Unit: 1648

had a reasonable expectation of success that the method steps of Ding would work in the method of Huiying.

Ding and Huiying are silent on:

- Temperature of inactivation. However, virus inactivation is well known in the art, as demonstrated by Liao. Liao discloses a method of purification and inactivation of JEV from Vero cell cultures, wherein formalin inactivation occurs at 4 degrees Celsius (col. 6, lines 55-58). One would have been motivated to use the teachings of Liao for example to inactivate viruses. One would have had a reasonable expectation of success given that Liao, Ding and Huiying inactivate JEV.
- The particular strain of JEV. However, it was known in the art at the time of invention that either Nakayama or Beijing-1 strain is used in JEV vaccines, as evidenced by Liao (col. 7, lines 7-9). One would have had motivation to use the Beijing strain because the strain was already being successfully used, and therefore would have had a reasonable expectation of success that the Beijing strain would work in Ding or Huiying's method.
- The use of inactivated JEV virus particles in diagnostic kits. One would have been motivated to use the particles of Ding or Huiying in a kit because antigenic compositions are routinely used for diagnostic purposes. Further, the diagnostic kit comprises the inactivated particle of instant claim 1. One would have had a reasonable expectation of success that the particles of Ding or Huiying would be effective as diagnostic reagents because of their antigenic nature.

Art Unit: 1648

Therefore, the invention as a whole would have been obvious to one of ordinary skill in the art at the time the invention was made.

### *Conclusion*

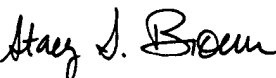
6. No claim is allowed.


Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Papers relating to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 located in Crystal Mall 1. The Fax number for Art Unit 1648 is (703) 308-4426. All Group 1600 Fax machines will be available to receive transmissions 24 hrs/day, 7 days/wk. Please note that the faxing of such papers must conform with the Notice published in the Official Gazette, 1096 OG 30, (November 15, 1989).

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Stacy S. Brown, whose telephone number is (703) 308-2361. The Examiner can normally be reached on Monday through Friday and alternate Wednesdays from 6:30 AM-4:00 PM, (EST). If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, James C. Housel, can be reached at (703) 308-4027. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

  
Stacy S. Brown  
June 7, 2002

  
HANKYEL T. PARK, PH.D  
PRIMARY EXAMINER